## 510(k) Summary

Prepared October 23, 2008

**K083162**

**STINGRAY SURGICAL PRODUCTS INC**
**801 APPLE TREE LANE**
**BOCA RATON, FL 33486**
**Tel 561-210-7582**
**Fax 561-210-5608**
**Contact: Mark McBrinn, President**

1. Identification of the Device:
   Proprietary-Trade Name: Stingray Electrosurgical Forceps
   Classification Name: Electrosurgical cutting and coagulation device and accessories
   Product Codes Product Code GEI
   Common/Usual Name: Bipolar Forceps
2. Equivalent legally marketed devices: ProMed Instruments GmbH DORO® Non-Stick Bipolar Forceps K070997
3. Indications for Use (intended use) Designed to grasp, manipulate and coagulate selected tissue for use in general surgical procedures. They are connected through a suitable bipolar cable with the bipolar output of an electrosurgical generator. Bipolar forceps must only be used with bipolar coagulation current. Coagulation is achieved using electrosurgical energy generated by the electro surgical generator unit and activated by a footswitch. The Stingray Forceps have not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures and should not be used for these procedures.
4. Description of the Device: These devices are bipolar forceps design for use in general surgical procedures. They are connected through a suitable bipolar cable with the bipolar output of an electrosurgical generator. The forceps are designed to grasp and manipulate selected tissues. Coagulation is achieved using electrosurgical energy generated by the electrosurgical generator unit and activated by a footswitch. They are constructed of stainless steel, a nylon coating, and a non-stick tip. The devices are provided non-sterile and must be autoclaved prior to use.
5. Safety and Effectiveness, comparison to predicate device. The results of bench and standards testing indicates that the new device is as safe and effective as the predicate devices.

6. Substantial Equivalence Chart

| Characteristic | ProMed Instruments GmbH DORO® Non-Stick Bipolar Forceps K070997 | Stingray Electrosurgical Forceps |
|---|---|---|
| Intended Use: | Bipolar electrosurgical procedures | SAME |
| Configuration | Coated handle, bipolar connector, stainless steel, and non-stick plated tip | SAME |
| Generator | Bipolar electrosurgical | SAME |
| Connector | 2 pin bipolar, insulated | SAME |
| Materials | Nylon coated stainless steel | SAME |
| Sterilization | Autoclave | SAME |
| Safety | 60601-2-2: Medical electrical equipment - Part 2-2: Particular requirements for the safety of high frequency surgical equipment | SAME |
| Standards | ANSI/AAMI HF18-2001: Electrosurgical Devices | SAME |

7. Conclusion

After analyzing bench and standards testing data, it is the conclusion of Stingray Surgical Inc. that the Stingray Electrosurgical Forceps are as safe and effective as the predicate devices, have few technological differences, and have no new indications for use, thus rendering them substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Stingray Surgical Products, Inc.
% Kamm & Associates
Mr. Daniel Kamm, P.E.
P.O. Box 7007
Deerfield, Illinois 60015

JAN 12 2009

Re: K083162
Trade/Device Name: Stingray Electrosurgical Forceps
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: December 17, 2008
Received: December 23, 2008

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K083162

Device Name: Stingray Electrosurgical Forceps

Indications For Use:
Designed to grasp, manipulate and coagulate selected tissue for use in general surgical procedures. They are connected through a suitable bipolar cable with the bipolar output of an electrosurgical generator. Bipolar forceps must only be used with bipolar coagulation current. Coagulation is achieved using electrosurgical energy generated by the electro surgical generator unit and activated by a footswitch. The Stingray Forceps have not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures and should not be used for these procedures.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



for mkm

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K083162